REMARKS

Applicant submits this Amendment in response to the Office Action mailed on June 29, 2005.

Claim 76 has been amended to clarify that the method of the invention provides for administration of water to the surface of the eye in an amount below that which will wash away the tear film of the eye. Claims 98 to 100 have been added to call for volumes of water that are administered to the eye. The subject matter of these claims was previously called for in claims 8 to 10 as originally filed. Claim 101 has been added to call for a subject suffering from dryness of the eye. Support for this feature is found throughout the specification and specifically for the term "dryness" is found on page 2, lines 14 to 22. No new matter is added by the present amendments.

REJECTIONS OF THE CLAIMS UNDER 35 U.S.C. §103(a)

The Examiner has rejected claims all pending claims as being obvious under 35 U.S.C. §103(a) over the combined disclosures of Junkel, U.S. Patent No. 5,620,633; Hahn, U.S. Patent No. 5,893,515; Hutson, U.S. Patent No. 5,588,564, and Embleton et al (WO 97/23177). Applicant traverses the rejection of the claims on this ground.

The present invention is a method for moisturizing the surface of the eye which method is by spraying small droplets of water onto the surface of the eye in a volume that maintains the integrity of the tear film. The method can be used to alleviate the symptoms associated with dryness of the eye, a condition in which the aqueous layer of the tear film has been reduced in volume, often resulting in discomfort such as itching, stinging, or burning sensations.

Prior methods of treating dry eyes typically utilized drops of a dry eye treatment formulation. This typically resulted in washing away the tear film of the eye and replacing it with a fluid having the composition of whatever was in the dry eye treatment formulation. The inventor of the present inventor has discovered, however, that improved moisturization of the eye can be achieved by administering water to the eye rather than a dry eye treatment formulation such as artificial tears, and that this improved moisturization is obtained by administering the water to the eye in a volume below that which will wash away the tear film on the surface of the eye. Moreover, the inventor has discovered that the optimal way to administer the water to the eye is by spraying small droplets of water on the eye.

The prior art does not disclose or suggest this invention, either taken singly or in combination.

The primary reference cited by the Examiner, Junkel, U.S. Patent No. 5,620,633, discloses a portable misting device for sunbathers and others involved in athletic pursuits. The device provides a cooling air current with atomized liquid mist, such as water, and directs the cooling air current in a direction set by a user. The device of Junkel, because it is meant to "combat the elements of heat and dehydration attendant with athletic activities and/or prolonged exposure to the sun" (see column 1, lines 15-19), is presumably meant to be used by directing such moist air current into an area occupied by a sunbather or one engaged in athletic pursuits or directly onto the surface of the body of such individual.

Junkel does not disclose moisturizing the surface of the eye, but rather pertains to cooling the body of one suffering from heat or dehydration due to sun exposure or sweating due to athletic endeavors. The Examiner states, in the previous Office Action mailed on March 17,

2005, in paragraph 5, on page 5, that Junkel does not disclose applying the mist to the face or to a subject in need of moisturizing the eye. Accordingly, Applicant submits that Junkel is not pertinent whatsoever to the present invention.

The secondary references cited by the Examiner, when combined with Junkel, do not disclose or suggest the present invention.

Hahn, U.S. Patent No. 5,893,515 discloses an apparatus for applying a mist of a comfort liquid or drug to the eye. It is noted that Hahn does not disclose administering water to the surface of the eye. Rather, Hahn refers to moistening liquids, comfort liquids, eye drop liquids, or liquid medium. Applicant has previously submitted two Declarations, one by Dr. Rachael Garrett on December 18, 2001, who testified that "Artificial tears, dry eye therapies, and comfort drops contain ingredients other than water that are essential for their beneficial effects", and one by Dr. Philip Paden on January 21, 2004, who testified that the use of water as a moisturizing agent for the eye represents a significant departure from previously accepted doctrines in the field of ophthalmology.

Additionally, Hahn discloses that the amount of comfort liquid that is to be administered to the eye is "a sufficient amount of comfort liquid or drug to saturate the eye without overflowing - about one drop." Applicant submits that this is a teaching away from the present invention, which calls for an amount that will not wash away the tear film of the eye. As disclosed in the present specification on page 2, a drop has a volume of about 20 to 25 μl which is sufficient to flood the eye and to wash away the tear film and replace it with the fluid that comprises the drop. This flooding the eye and washing away the tear film occurs even without

overflowing the eye. Thus, the volume prescribed by Hahn is in direct contrast to that called for in the present claims.

Hutson, U.S. Patent No. 5,588,564, discloses an apparatus for providing a mist of a liquid to the surface of the eye. Hutson, like Hahn, does not disclose the administration of water as a moisturizing agent for the surface of the eye. Rather, Hutson discloses the delivery of "a fluid" (see Abstract, and column 2, line 6), an "eye wash solution" (see column 1, line 51), or "an eye solution mist" (see column 1, line 65). Additionally, Hutson is silent as to the volume of liquid that is dispensed to the eye.

Embleton et al (WO 97/23177) has been discussed in several past amendments. Embleton is concerned with the problem of over-administering a treatment fluid to the surface of the eye. Such overdosing results in two deleterious effects. The first such deleterious effect is that providing a medicament in an amount of liquid that is greater than that which can be retained by the eye results in wastage of the medicament and a lack of precision in dosage. The second and more serious deleterious defect is that providing a medicament in a too large volume of fluid to the eye results in runoff of the medicament down the tear duct and into the nasal passages where it can be inhaled into the systemic circulation of a patient, with potentially disastrous effects depending on the nature of the medicament. As a solution to this problem, Embleton discloses an apparatus that delivers a treatment liquid in the form of a jet or a stream to the surface of the eye which delivers a small volume of a treatment fluid so as not to flood the eye.

As discussed previously by Applicant, Embleton teaches away from the present invention which calls for spraying a mist as Embleton discloses the necessity of administering the fluid as a jet or stream. Further, Embleton does not disclose the administration of water. As

argued previously by Applicant and as testified to by Dr. Rachael Garrett in her Declaration filed on December 18, 2001, the disclosure cited by this Examiner and the previous Examiner does not refer to administration of water, but rather to administration of a treatment fluid based on water.

Applicant respectfully submits that none of the prior art references disclose or suggest the administration of water to the eye in order to moisturize the surface of the eye. Further, Applicant respectfully submits that none of the prior art references disclose or suggest moisturizing the eye by administering an amount of fluid that is less than that which will wash away the tear film on the surface of the eye. Additionally, several of the cited references teach away from the claimed invention, as discussed above. Accordingly, Applicant submits that the cited prior art is insufficient to establish a prima facie case of obviousness and the Examiner is requested, therefore, to withdraw the rejection of the claims on this ground and to issue a Notice of Allowance of the claims.

ADDITIONAL COMMENTS

Applicant submits that, even if the Examiner feels that the cited prior art references are sufficient to establish prima facie obviousness of the claimed invention, Applicant has overcome this basis of rejection by the submission of numerous Declarations. The Examiner's attention is brought to the following previously submitted Declarations and other submissions.

Applicant has submitted, on January 30, 2004, a Declaration by Dr. Philip Paden who testified that the present invention is a departure from previous accepted doctrine in ophthalmology.

Applicant has submitted, on January 30, 2004, a Declaration by Dr. William Mathers who testified regarding unexpected advantageous properties obtained by the method of the invention.

Applicant has submitted, on January 30, 2004, a Declaration by Dr. Darwin Liao who testified regarding unexpected advantageous properties obtained by the method of the invention.

Applicant has submitted, on May 10, 2005, a Second Declaration by Dr. William Mathers who testified the invention addresses and solves a long-standing unresolved problem pertaining to the treatment of patients with symptoms due to dry eyes.

Applicant also has submitted, with the Amendment filed on January 30, 2004, an article in Exchange & Commissary News, 43(1):6 (January 15, 2004) that discloses that the U.S. military is using a commercial version of the invention and is supplying it to troops in Iraq who have found it to be superior to other products in moisturizing their eyes in that harsh desert climate. This establishes the commercial success of the invention and acceptance of the product embodying the invention by the marketplace.

Applicant submits, accordingly, that even if the prior art establishes prima facie obviousness of the invention, Applicant has submitted evidence sufficient to overcome such prima facie obviousness. Accordingly, Applicant respectfully requests the Examiner to withdraw the rejection of the claims as being obvious in view of the prior art.

Conclusion

Applicant respectfully requests the Examiner to withdraw the rejection of the claims and to promptly issue a notice of allowance for this application.

Respectfully submitted,

Howard Eisenberg
Reg. No. 36,789
2206 Applewood Court
Perkasie, PA 18944
(215) 453-9237
Attorney for Applicant

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on September 6, 2005.

Dated: 9/6/05

Howard M. Eisenberg